REMARKS

In an Official Action dated July 16, 2002, the Examiner rejected claims 1-6 as anticipated by or obvious in light of Alexander 5,964,735 and Gibbs 5,085,640. Applicants request that the Examiner reconsider the rejection of claims 1-6 and favorably consider newly presented claims 14-44 in light of the following discussion.

§112 Rejections

Applicants believe that the rejection of §112 claim was incorrect because claim 1 is clear and definite. Every patient necessarily has skin. Therefore, there is no ambiguity when referring to "the skin of the patient". Nonetheless, in order to move prosecution forward claim 1 has been amended to delete the reference to "the skin of" from claim 1. Accordingly, Applicants request that the Examiner reconsider the §112 rejection of claim 1.

With respect to claim 2, the Examiner contends that there is insufficient antecedent basis for the term fluid. Applicants disagree. Claim 1 recites the steps of collecting fluid and expelling the fluid. Claim 2 recites how the fluid is expelled. Since claim 1 recites the fluid and since claim 2 depends from claim 1, there is clear antecedent basis for the term fluid in claim 2. Accordingly, Applicants request that the Examiner reconsider the §112 rejection of claim 2.

With respect to claim 6, the Examiner contends that there is insufficient antecedent basis for the term "the pH level". Again, Applicants disagree. Section 112 simply requires that the claims by clear and definite. There is no ambiguity raised by referring to "the pH level" because every fluid has a pH level. It is an inherent property of every fluid. There is no other pH level mentioned that could cause any confusion. Accordingly, since claim 6 is clear and definite, it meets the statutory requirement. Therefore Applicants request that the Examiner reconsider

the §112 rejection of claim 6.

§102 Rejections

The Examiner rejected claims 1-6 as anticipated by Alexander 5,964,735. However, Alexander operates quite differently from Applicants device. Therefore, in light of the claim amendments Applicants request that the Examiner reconsider the rejection of claims 1-6 and favorably consider claims 14-55.

Turning now to the device disclosed in Alexander '735, the device includes a housing 1 having a forward end through which a needle 7 projects. Also at the forward end of the device is a separate opening 3 that serves as a discharge port for discharging the fluid after it is collected.

The needle 7 extends into the barrel 1 of the device and through a piston 16 on the front end of a plunger 15. The rearward end of the needle forms a head that extends to the back end of a cavity 11 formed in the plunger 15. The plunger is pulled rearwardly to draw fluid into the barrel. The fluid flows into the barrel through a side opening 91 (See Fig. 5) in the needle so that the fluid is collected in the space forward of the piston on the plunger.

As the plunger 15 is pulled rearwardly, it slides over the needle 7 until the head 31 of the needle engages the front end of the cavity 11 in the plunger. At this point, the head 31 of the needle butts up against the inside of the plunger so that pulling the plunger further also pulls the needle rearwardly. To retract the needle into the housing, the plunger must be pulled all the way to the rearward end of the barrel so that it engages an internal flange 4 in the barrel.

After the needle is retracted, it tilts off to the side so that it is misaligned with the opening at the front of the barrel. To expel the collected fluid, a cap 5 is

removed from the discharge port at the front of the syringe and the plunger is pushed forwardly. In doing so, the plunger also drives the retracted needle forwardly. However, since the needle is tilted to the side, the needle does not go back through the needle opening; instead, it engages the front wall of the barrel, and is crushed as the plunger drives forward.

In contrast, claim 1 recites a methodology that includes a device having a plunger wherein the needle is retracted into the plunger to shield the needle. This is in sharp contrast to the Alexander device in which the device is pulled into the housing and then crushed. In fact, since the device in Alexander uses the plunger to pull the needle into the housing, it is hard to imagine how Alexander could be modified to retract the needle into the plunger. Since Alexander does not teach or suggest retracting the needle into the plunger, and since such a feature is contrary to the operation of the Alexander device, claim 1 is patentable over Alexander.

Claims 2-6 and 14-24 depend from claim 1 so that they are patentable over Alexander for at least the reasons recited above in connection with claim 1. Further, as discussed below, the features in the dependent claims are further patentably distinct from Alexander.

Claim 14 recites the step of biasing the needle rearwardly. In Alexander's device nothing biases the needle rearwardly. Instead, the needle is fixed in an axial position until the operator pulls the plunger rearwardly to retract the needle. Further, in light of the way that Alexander crushes the needle to prevent re-use and retracts the needle by pulling the plunger, it does not appear that Alexander could be modified to include a biasing element. Accordingly, claim 14 is further patentably distinct from Alexander.

Similarly, Alexander does not teach or suggest releasing the needle to allow a biasing element to automatically retract the needle, as recited in claim 15.

Therefore, claim 15 is further patentably distinct from Alexander.

As shown in Figs. 1-3 and 6-7d, several of Applicants embodiments operate by releasing the needle in response to rearward displacement of the plunger, so that a biasing element retracts the needle. Claim 16 depends from claim 15, which recites that a biasing element retracts the needle rearwardly. Claim 16 further specifies that the step of releasing the needle occurs in response to displacing the plunger rearwardly. This feature further distinguishes claim 16 from the prior art.

Claim 18 recites the step of maintaining the needle in a fixed axial position relative to the housing while a majority of the fluid is collected in the housing. In contrast, Alexander pulls the needle rearwardly by pulling on the plunger, which is how the fluid is collected. In other words, the needle is being pulled rearwardly during most of the fluid collection using the Alexander device. The only time that the needle may stay stationary is the length of stroke between the time that the plunger is first pulled rearwardly, until the plunger engages the rearward head on the needle, as shown in Fig. 2. As can be seen, this length of travel is much less than the full length of travel required to fill the device. Accordingly, claim 18 is further patentably distinct from Alexander.

Claim 20 recites that the housing has a port and that the steps of collecting fluid and expelling fluid occur through the port. In contrast, Alexander requires a port 12 for collecting fluid and a separate port 3 for expelling the fluid. Accordingly, claim 20 is further patentably distinct from Alexander.

Claim 21 recites the step of venting air from the housing during the step of collecting fluid. As described in the application, several of Applicants' embodiments include a vent for venting air while the fluid is being collected. See e.g. element 336 in Fig. 8. There is no teaching or suggestion in Alexander of venting air while the fluid is being collected. Accordingly, claim 21 is further

patentably distinct from Alexander.

The application also discloses several embodiments in which the needle assembly is an add-on assembly that can be added onto a separate housing, such as a syringe. The add-on needle assembly allows the device to operate as a fluid collection device. Claim 22 recites features of such an add-on needle assembly. For instance, claim 22 recites a needle assembly comprising a hub and the needle, wherein the hub has a connector that cooperates with a connector on the housing. Nothing in Alexander teaches or suggests such an add-on needle assembly. Accordingly, claim 22 is further patentably distinct from Alexander. Similarly, claim 23, which depends from claim 22 recites the step of removing the hub from the barrel prior to expelling the fluid from the housing. This further distinguishes claim 23 from Alexander.

As shown in Figs. 5a-5d, one aspect of Applicants' invention also includes providing a plunger having a piston, wherein the method includes removing the piston from the plunger. This allows the needle to be retracted while maintaining the fluid in the housing. After the needle is retracted, the plunger can be re-advanced to engage the piston to expel the fluid. Nothing in Alexander teaches or suggests such features. Accordingly, claim 24, which recites the step of removing the piston from the plunger, is further patentably distinct from Alexander.

Claim 26 recites that the step of collecting comprises displacing the plunger in response to the fluid pressure of the fluid being collected. For instance, Applicants' devices may be configured to collect arterial blood, so that the arterial pressure of the blood is sufficient to displace the plunger rearwardly as the blood flows into the housing. Nothing in Alexander teaches or suggests such a feature. Accordingly, claim 26 is further patentably distinct from Alexander.

The Examiner also rejected claim 1 as anticipated by Gibbs 5,085,640.

However, Gibbs is a significantly different device. For instance, Gibbs is directed to a typical blood collection device that uses separate blood collection tubes commonly referred to as Vacutainers. The blood is collected into a Vacutainer, which is removed from the housing after it is filled. The needle is then retracted into the housing. Nothing in Gibbs teaches or suggests using a device having a plunger because there is no way that a plunger could be used with such Vacutainers. Since there is no teaching or suggestion of using a plunger, there is obviously no teaching or suggestion of retracting a needle into a plunger. Accordingly, claim 1 and dependent claims 2-6 and 14-26 are patentably distinct from Gibbs 5,085,640.

Applicants also request that the Examiner favorably consider newly present claims 27-58. Independent claim 27 recites the steps of providing a biasing element to bias the needle rearwardly, releasably retaining the needle in a fixed axial position against the bias, and releasing the needle so that the biasing element displaces the needle into the retracted position. As discussed above in connection with dependent claims 14-17, nothing in Alexander teaches or suggests such steps. In addition, as discussed previously, Gibbs is a very different structure that uses a removable Vactutainer tube to receive the collected blood. The Vacutainer is then removed from the housing before the needle is retracted into the housing. Therefore, Gibbs does not teach or suggest the step of expelling fluid from the reservoir in the housing after the needle is retracted. Accordingly, claim 27 and dependent claims 28-41 are patentable over the prior art of record.

Referring to independent claim 42, the claim is directed to the use of a device that incorporates an add-on needle assembly. As discussed above in connection with claims 22 and 23, nothing in Alexander teaches or suggests such steps. Similarly, Gibbs does not teach or suggest such steps. Further, claim 42 recites providing a device having a plunger, and as discussed above Gibbs does not teach or suggest the use of a device that includes a plunger. Accordingly, claim 42 and dependent claims 43-58 are patentable over the prior art of record.

In light of the foregoing, Applicant believes that this application is in form for allowance. The Examiner is encouraged to contact Applicant's undersigned attorney if the Examiner believes that issues remain regarding the allowability of this application.

Respectfully submitted,

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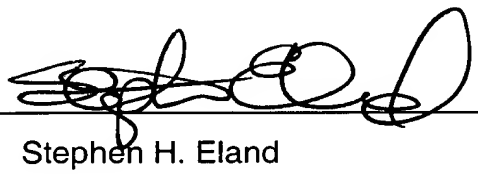
By 

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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this Response and accompanying papers are being deposited on **November 18, 2002** with the United States Postal Service as first-class mail in an envelope properly addressed to COMMISSIONER OF PATENTS AND TRADEMARKS, Washington, DC 20231

November 18, 2002
Date of Certificate

Christine Edinger
Christine Edinger

Petition for Extension Under 37 CFR §1.136(a)

Applicant's undersigned Attorney hereby petitions for an extension of time of **ONE** month beyond the time period set in the last office communication. The proper fee is enclosed as identified in the enclosed Fee Transmittal form.

November 18, 2002
Date of Certificate

Stephen H. Eland
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ATTACHMENT A

1. (Amended) A method for withdrawing a fluid sample from a patient, comprising the steps of:

   a. providing a sampling device having a housing, a plunger and a needle having a sharpened tip for piercing ~~the skin of~~ the patient~~.~~;

   b. collecting fluid from the patient in the housing;

   c. retracting the needle into the plunger so that the sharpened tip of the needle is shielded to prevent inadvertent contact with the sharpened tip; and

   d. expelling the fluid from the housing after the needle is retracted.

2. (Amended) The method of claim 1 wherein ~~the device comprises a plunger displaceable within the housing and~~ the step of expelling fluid comprises the step of displacing the plunger within the housing.